

## **The role of GnRH analogues(GnRH-a) in improving outcome in women undergoing super-ovulation (SO) and intra-uterine insemination (IUI) after surgical correction of minimal to mild endometriosis: a randomized control trial.**

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**CONTEXT** Endometriosis is an estrogen dependent inflammatory condition with complex immunological, hormonal and systemic factors influencing its pathogenesis. The altered immunologic milieu of cytokines, auto-antibodies, reactive-oxygen species, prostaglandins create a hostile environment in the peritoneal cavity which may impair ovulation, gamete interaction, fertilization, early embryo development and implantation.

**OBJECTIVE** The hypoestrogenic states as caused by GnRH-a may suppress the altered immune status and improve fecundity in women with endometriosis.

**METHODS** Design: Randomized controlled trial. Sample size: Ninety infertile women with minimal or mild endometriosis undergoing SO and IUI after laparoscopic surgery. All patients underwent a standard three port laparoscopy. Those with minimal or mild endometriosis (revised ASRM criteria) underwent surgical treatment by either excision or ablation. Thereafter block randomization was used. Period of study: December 2012 to June 2014 at AIIMS, Delhi. The trial has been registered with the Clinical Trials Registry – India, CTRI NO. CTRI/2016/08/007162

**PATIENT(S)** Inclusion criteria: Infertile women with minimal or mild endometriosis post laparoscopic surgery, age < 36 yrs. Exclusion criteria: Pelvic inflammatory disease, Poly-Cystic Ovarian Syndrome, endometrial polyp, sub-mucous myoma, FSH >10 IU/ml, recurrent endometriosis, male factor infertility.

**INTERVENTION(S)** Patients in study group received a single dose of GnRH analogue (leuprolide acetate) 3.25 mg s.c. within 48 hrs after surgery whereas the control group did not. Thereafter patients in both the arms underwent SO and IUI from the next menstrual cycle.

**MAIN OUTCOME MEASURE(S)** Primary outcome-clinical pregnancy rates. Secondary outcome-number of follicles > 18mm, endometrial thickness, dose of gonadotropin used, days of stimulation

**RESULT(S)** On intention to treat analysis the pregnancy rate (PR) was 15.5% in GnRH-a group and 17.7% in non GnRH-a group. The difference of proportions was 2.2% with 95% confidence interval (CI) of -13.2% to 17.6%. (p value 0.77). Overall the PR was 21.9% in the GnRH-a group and 23.8% in the non GnRH-a group (p value 1.00).

**CONCLUSIONS** Adding GnRH-a for suppression of endometriosis showed no significant improvement over surgical management. Though GnRH-a may be equally effective as surgery, it delays resumption of menstrual cycles, impeding chances of pregnancy, adds to the cost of therapy.

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